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10/583,491

06/15/2006

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EXAMINER

PENG, BO

ART UNIT

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1648

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/583,491 | Applicant(s) BIANCHI ET AL. | |
| | Examiner BO PENG | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. 1.Claims 1-36 are pending. Note: A prompt response to *Election/Restrictions* is encouraged by the examiner to expedite the prosecution of this case.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 23-28 and 35, drawn to the technical feature of a peptide-carrier conjugate comprising an OMPC and a plurality of modified peptides.

Group II, claim(s) 1-22 and 31-34, drawn to the technical feature of a method for making a peptide conjugate comprising OMPC and peptides.

Group III, claim(s) 29 and 30, drawn to the technical feature of a method of inducing an immune response in a mammal using the product of Group I.

Group IV, claim(s) 36, drawn to the technical feature of a method for determining the favorable pI range for conjugation peptides to a carrier.

4. The inventions listed as Group I-IV are not related to a single general inventive concept under PCT Rule 13.1 because, under PCT rule 13.2, they lack the same or corresponding special technical features. The technical feature of the product of Claim 24 appears to be of a peptide-carrier conjugate comprising an OMPC and a plurality of modified peptides. Tolman et al teach a HIV vaccine comprising V3-loop HIV peptide conjugated to OMPC carrier, see e.g. Abstract. (In. J. peptide & protein research, 1993, 41:435-466, cited in IDS). Tolman et al also teach of a method for making a peptide conjugate comprising OMPC and V3-loop peptides, and a method of inducing an immune response in a mammal using the peptide conjugate comprising OMPC and V3-loop peptides. The technical feature of Group I cannot be a special technical feature under PCT Rule 13.2 because the technical feature is shown in the prior art. As set forth above, each group of Groups I-IV requires a technical feature that is not required by any of the other groups. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

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Species Election

5. This application contains claims directed to more than one species of the generic invention. These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

6. If Group II above is elected, Applicant is required to elect one pathogen from claims 5 and 6, which is:

- (1) Haemophilus influenza,
- (2) hepatitis A virus,
- (3) hepatitis B virus, or
- (4) hepatitis C virus,
- (5) HIV,
- (6) human papilloma virus,
- (7) measles,
- (8) mumps,
- (10) rubella,
- (11) varicella,
- (12) rotavirus,
- (13) Streptococcus pneumonia; OR
- (14) Staphylococcus aureus (Claims 5 and 6).

7. Applicant is required to further elect one reagent for conjugating the peptide to the carrier, which is:

- (15) sulfosuccinimidyl 4-(N- maleimidomethyl)cyclohexane-1-carboxylate (sSMCC),
- (16) N-maleimidobenzoyl-N-hydroxysuccinimide ester (MBS),
- (17) glutaraldehyde,
- (18) 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide (EDCI),
- (19) Bis- diazobenzidine (BDB), OR
- (21) N-acetyl homocysteine thiolactone (NAHT).

8. Applicant is required to further elect one carrier, which is:

- (22) OMPC (outer membrane protein complex of Neisseria meningitidis),
- (23) BSA (bovine serum albumin);
- (24) OVA (ovalbumin),
- (25) THY (bovine thyroglobulin),
- (26) KLH (keyhole limpet hemocyanin),
- (27) tetanus toxoid protein,
- (28) HBs (Hepatitis B virus surface antigen protein),
- (29) HBc (Hepatitis B virus core antigen protein),
- (30) rotavirus capsid proteins,

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- (31) the L1 protein of the Human Papilloma Virus VLP type 6,
- (32) the L1 protein of the Human Papilloma Virus VLP type 11,
- (33) the L1 protein of the Human Papilloma Virus VLP type 16, OR
- (34) Dextran.

9. If Group I above is elected, Applicant is required to the modified peptide have a sequence of:

- (a) SEQ ID NOs:2 and 4;
- (b) SEQ ID NO: 6; OR
- (c) SEQ ID NO:s 8-11

10. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(I) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. In the instant case, the peptide-carrier conjugates do not share either common activities or common structures. Therefore, these species do not relate to a single general inventive concept under PCT Rule 13.1 and PCT Rule 13.2.

11. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

10. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

12. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

13. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

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Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

15. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/

Examiner, Art Unit 1648